

REMARKS

This responds to the Final Office Action mailed on January 28, 2009.

Claims 1, 16, 30 and 34-35 are amended. Support for the amendments to the claims can be found in the specification as originally filed, see, for example, page 3, lines 9-10; page 4, lines 10-12; page 5, lines 4-13 and 24-28; and claims 33 and 37. Applicant respectfully submits that no new matter is added by way of amendment. Claims 1-11, 14-26, 30-33, 34-40 and 44-45 are pending.

The 35 U.S.C. § 112 Rejection

Claims 1-11, 14-26, 30-40, 44 and 45 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant has amended claims 1, 16, 30 and 35 to better describe the subject matter recited in the claims. For example, amended claim 1 recites: “[a]n apparatus comprising: an electrical lead comprising a lead body and an electrical conductor; and an electrode coupled to the electrical conductor, wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including three or more layers, with a first layer adjacent the surface of the electrode including an insulative material while leaving an uninsulated region of the electrode and a second layer adjacent the first layer and not adjacent to the surface of the electrode including at least one pharmacological agent, and a third layer above the second layer, wherein the third layer includes at least one pharmacological agent.” Thus, the first layer leaves an uninsulated region or uncoated region of the electrode, while the second layer is adjacent to the first layer, but is not adjacent to the electrode. And a third layer is above the second layer. Applicant respectfully submits that the claims, as amended, are definite and comply with § 112(2). Thus, Applicant respectfully requests withdrawal of the rejection of the claims under 112(2).

The 35 U.S.C. § 103 Rejection

Claims 1-11, 14-26, 30-40, 44 and 45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolz et al. (U.S. Patent No. 5,964,794) in view of Steinhaus et al. (U.S. Patent No. 6,546,292). Applicant respectfully traverses this rejection.

Claims 1, 16, 30 and 35

Bolz et al. disclose an electrode with a coating covering the entire electrode. See, for example, the Figures, in particular the Figure on the face page of the patent and Figure 5. Additionally, claim 1 recites "...a thin, specifically functionalized organic coating (1b; 1c'; 1b", 1d; 1b"; 17) forming the entire outer surface of the stimulation electrode" [emphasis provided].

Thus, Bolz et al. do not disclose "a first layer adjacent the surface of the electrode including an insulative material while leaving an uninsulated region of the electrode." Furthermore, Bolz et al. do not disclose a first layer adjacent the surface of the electrode including an insulative material while leaving an uninsulated region of the electrode and a second layer adjacent the first layer and not adjacent to the surface of the electrode including at least one pharmacological agent..." Thus, Bolz et al. do not disclose an electrode in which a portion of the electrode is not covered by at least the first two layers. Furthermore, the explicit disclosure in Bolz et al. to coat the entire outer surface of the stimulation electrode (see, for example, claim 1 and Figure 5) teaches away from leaving a portion of the electrode uncoated with the first or second layer.

Steinhaus et al. disclose a layered electrode in which "the electrode tip has an outer layer of microporous material...which covers a layer of insulating material...[that has] at least one perforation through the thickness of the material" (Abstract). At column 5, lines 9-12, Steinhaus et al. disclose that "cover" is defined as a material that coats or otherwise covers an underlying surface. Thus, the outer layer of the two layers of Steinhaus et al. covers the electrode. Therefore, Steinhaus et al. do not disclose a "first layer adjacent the surface of the electrode including an insulative material while leaving an uninsulated region of the electrode and a second layer adjacent the first layer and not adjacent to the surface of the electrode including at least one pharmacological agent..." Therefore, Steinhaus et al. also do not disclose an electrode in which a portion of the electrode is not covered by the first two layers.

Thus, Applicant respectfully submits that the combination of the cited documents do not disclose or suggest each claim limitation. Applicant respectfully notes that the examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. 2142. When determining whether a claim is obvious, an examiner must make "a searching comparison of the claimed invention – including all its limitations – with the teaching of the

prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Moreover, as the Supreme Court recently stated, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)).

Claims 2-11 and 14-15

Claims 2-11 and 14-15 include each limitation recited in claim 1 and are therefore not obvious over the cited documents since the cited documents do not teach or suggest all of the limitations of the rejected claims.

Claims 17-26

Claims 17-26 include each limitation recited in claim 16 and are therefore not obvious over the cited documents since the cited documents do not teach or suggest all of the limitations of the rejected claims.

Claims 31-34

Claims 31-34 include each limitation recited in claim 30 and are therefore not obvious over the cited documents since the cited documents do not teach or suggest all of the limitations of the rejected claims.

Claims 36-40 and 44-45

Claims 36-40 and 44-45 include each limitation recited in claim 35 and are therefore not obvious over the cited documents since the cited documents do not teach or suggest all of the limitations of the rejected claims.

Thus, Applicant respectfully requests withdrawal of the rejection of the claims under 103(a).

CONCLUSION

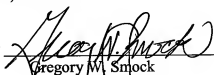
Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6905 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6900

Date July 28, 2009

By 
Gregory M. Smock
Reg. No. 60,208

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 28, 2009.

Nicole Jack

Name


Signature